REMARKS

Applicants have amended the specification in response to the Examiner's objection regarding correct trademark usage and have amended the claims in response to several rejections raised by the Examiner. None of the amendments introduce new matter, and basis for the amendments is found in the specification as identified below.

Rejection under 35 U.S.C. § 101:

Claim 1, and those dependent therefrom, were rejected under 35 U.S.C. § 101 because the claim as written did not sufficiently distinguish the claimed composition over an LT-producing *E. coli* as it exists in nature. The Examiner kindly suggested Applicants amend the claim to indicate the hand of the inventor by inserting "isolated" or "purified" before "native *E. coli* heat-labile toxin (LT)".

Applicants have amended Claim 1 by adding the term "isolated" as suggested by the Examiner. Basis for "isolated" is found in section [0037] which teaches how the inventors isolated native LT.

In view of this amendment to Claim 1, Applicants believe they have effectively traversed the present rejection of Claim 1, and those dependent therefrom, and submit that the claims now in the application are in full compliance with the requirements of 35 U.S.C. § 101. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 112, second paragraph:

Claims 3, 6, 7, 9 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically the Examiner pointed out that there is no antecedent basis for the term "adjuvant" in dependent Claims 3, 6, 7, 9 and 10 because the term was deleted in the June 16, 2006, preliminary amendment to Claim 1. Applicants apologize for this careless oversight. In the present amendment, the term "adjuvant" is reintroduced into Claim 1 to provide antecedent basis for the term in dependent Claims 3, 6, 7, 9 and 10.

The Examiner also rejected Claim 3 based on Applicants' use of the term "derived" because it does not clearly convey what is being claimed. Applicants understand the Examiner's concern and have amended Claim 3 by removing the term "derived" and reciting traditional Markush claim language that is more appropriate.

In view of the amendments to Claims 1 and 3, Applicants believe they have effectively traversed the present § 112 rejection and submit that the amended claims are in full compliance with the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 102:

Claims 1 and 6 were rejected under 35 U.S.C. § 102 as being anticipated by Ruedl *et al.* (*Vaccine* 14: 792-798, 1996). Ruedl *et al.* disclose native whole *E. coli* heat-labile toxin (LT) and cholera toxin (CT) compositions. They report mucosal and systemic murine immune responses of such compositions after oral administrations and speculate

that such compositions offer an efficient means to induce both mucosal and systemic immune responses after cautioning about the toxic affects of such compositions (conclusion 3, page 978). Ruedl *et al.* do disclose the utility of such compositions in fowl or whether the toxicity seen in mammals is also observed in fowl.

To constitute anticipation, all material elements of a claim must be found in one prior art reference. *In re Marshall*, 577 F2d 301 (CCPA 1978). Applicants' amended claims are now limited to LT compositions "wherein the composition does not produce any pathogenic effects in the vaccinated bird." Because Ruedl *et al.* do disclose such compositions for use in vaccinating bird which do not show any pathological consequences after administration, Applicants assert Ruedl *et al.* do not anticipate their invention.

Claims 1, 6, and 7 were rejected under 35 U.S.C. § 102(e)(1) as being anticipated over Mason et al. (US 2003/0176653). Applicants wish to respectfully point out that the Examiner has misread Mason *et al.* regarding what it discloses and teaches about LT. The passages referenced in the Examiner's Office Action appear to anticipate the instant invention due to the reference's somewhat careless use of abbreviations. Upon a close review of the Abstract and Sections [0014, 0081, 0082, and 0083], it is clear that Mason *et al.* disclose the vaccinal use of mutant non-pathogenic LT and non-pathogenic subunits of LT and not whole native pathogenic LT as claimed by Applicants. This is because Mason *et al.* understand the state of the art concerning the pathogenic nature of whole native LT. Examples 10, 12, 13, 14, 15, 17 and 18 where Mason *et al.* teach the expression of mutant holo-LT reinforce that the reference does not disclose and in fact

teaches away from using native whole LT as an immunogen or adjuvant due to its highly pathogenic properties.

In view of the amendments and the above discussion, Applicants believe they have effectively traversed the present § 102 rejection and submit that the amended claims are in full compliance with the requirements of 35 U.S.C. § 102. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 103:

Claims 2-5 and 8-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mason *et al.* (US 2003/0176653) as applied against the § 102 rejection and in further view of Qin et al. (CN 1333370A) and Huang et al. (*FASEB J.* 13, 4 part 1: p.A290, 12 March 1999).

Applicants understand that all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

As discussed above, Applicants believe the Examiner misread Mason *et al.* because Mason *et al.* does not disclose whole native LT as a useful immunogen or adjuvant for birds in the absence of pathogenic effects. In addition, Applicants contend that Mason *et al.* teaches away from the instant invention because the reference teaches and motivates the skilled artisan to use non-toxic analogs or subunits of LT rather than whole native LT as Applicants have claimed. Because neither secondary reference discloses this key technical feature, the secondary references are inadequate to support a *prima facie* case of obviousness absent the primary reference supplying the teachings or

motivation to use whole native LT as an immunogen or adjuvant in birds in the absence of pathogenic effects.

In view of the amendments and remarks presented with this response, it is urged that the rejections of record are overcome and the present application is in condition for allowance. Favorable consideration of this application is requested.

Respectfully submitted,

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